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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,189	09/30/2004	Paul Howley	22996	7534
535 7590 05/30/2007 K.F. ROSS P.C. 5683 RIVERDALE AVENUE SUITE 203 BOX 900 BRONX, NY 10471-0900			EXAMINER HURT, SHARON L	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 05/30/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/510,189

Applicant(s)

HOWLEY ET AL.

Examiner

Sharon Hurt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-25 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-18, 20-25 and 28-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-18, 20-25 and new claims 28-33 are pending and under examination on the merits. Claims 19 and 26-27 have been canceled.

### ***Response to Amendment***

Applicant's amendments filed March 8, 2007 have been entered. Applicant added new claims 28-33 for examination.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 26-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **moot**. Claims 26-27 have been canceled. New claims 28-33 (replacing claims 26-27) have incorporated method steps thereby overcoming the rejection.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13-18, 20-25 and new claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al. in view of Cohen et al. and further in view of Men et al. as

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previously stated for claims 1-8, 10-11 and 13-25 in the Office Action sent January 9, 2007.

This rejection is **maintained**. Please note that claim 9 was inadvertently omitted from the previous 103 rejection in the Office Action sent January 9, 2007. The rejection of claim 9 under 35 U.S.C. 103(a) was maintained from the Office Action sent June 5, 2006.

The claimed invention is described in the previous Office Action. The teachings of Paoletti, Cohen and Men are described in the previous Office Action.

Applicant's arguments filed March 8, 2007 have been fully considered but they are not persuasive. Applicant argues "Cohen et al does not disclose the insertion into a poxvirus of at least two foreign genes which are homologous in comparison to each other at two different insertion sites in the same poxvirus". Cohen teaches insertion of DNA from recombinant fowlpox virus in two different sites (col. 4, lines 44-46). Applicant also argues "There is no disclosure or suggestion in Cohen et al of inserting two homologous genes, such as those from Dengue Virus, into the same poxvirus". The instant claims are drawn to 50% to 75% homology, which leaves up to 50% non-homology for said genes. Applicant further argues "that they have discovered that these recombinant poxviruses prepared according to the present invention are surprisingly stable immunogens and are not subject to homologous recombination as would have been expected". There is no evidence that this is what a person having ordinary skill in the art expected. If there is an unexpected result, it is limited to the PrM gene of Dengue as described in the example in the specification.

Applicant argues "that Paoletti et al discloses insertion of two homologous genes into the same site of a viral vector in no way is suggestive of the presently claimed invention". Applicant also argues that "events between two or more homologous genes located at different sites as in

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the present invention would be expected to be high, and conversely events between two abutting homologous genes in Paoletti et al would be expected to be low". Examiner disagrees, because there is no minimum distance between insertion sites recited in the instant claims. Therefore, two insertion sites could be separated by only a few base pairs. Frequency of recombination also depends on the degree of homology however, the claims encompass as little as 50% homology. Applicant further argues that "there is no suggestion in Paoletti et al, Cohen et al or Men et al, where these references are taken individually or cumulatively of the insertion into a poxvirus of at least two foreign genes which are homologous in comparison to each other at two different insertion sites in the same poxvirus".

Paoletti teaches a recombinant poxvirus containing foreign DNA from flavivirus, such as dengue, wherein the foreign genes were inserted at different locations on the vaccinia virus genome (Abstract and Example 5). Cohen teaches about insertion of DNA from recombinant fowlpox virus in two different sites (col. 4, lines 44-46). Men teaches the use of the highly attenuated, replication-deficient modified vaccinia Ankara (MVA) as a vector to construct recombinants for expression of glycoproteins of one or more dengue virus (Abstract). The combination of references teaches the instant claimed invention.

Claim 12 is free of the art.

### ***Conclusion***

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

May 17, 2007

A handwritten signature in cursive script, reading "Bruce Campell".

**BRUCE R. CAMPELL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600**